

REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1, 39-47, 49, 50 and 68 presently appear in this application, with claim 68 being withdrawn from consideration by the examiner, and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Upon allowance of an elected product claim, it is understood that nonelected process claims which depend from the allowable product claim or otherwise include all the limitations of the allowable product claim would be rejoined under rejoinder practice pursuant to MPEP 821.04.

Nonelected claims 51-62, 66, 67, 71, 72, 76 and 77 are being cancelled without prejudice to refiling in a divisional application.

Claims 1, 39-47, 49 and 50 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Furutani et al. (WO 02/052029) in view of Scholz et al. (WO 03/000878), Harlow et al. (Antibodies: A Laboratory Manual, Cold Spring Harbor Press, 1988, Chapter 5, pages 53-137) and Sambrook et al. (Molecular Cloning: A Laboratory Manual Second Edition, Cold Spring Harbor Laboratory Press, 1989, page 17.3). The examiner indicates that applicants' arguments have been carefully considered but are not persuasive

because the examiner asserts that folding factor fusion proteins were known in the art as successful immunogens and it would have been obvious to add an adjuvant to the fusion protein of Furutani et al. because Scholz et al. teach that fusion proteins can be used to make antibodies to a target antigen and Sambrook teaches that it is useful to produce a fusion protein for use as an antigen. This rejection is respectfully traversed.

One of ordinary skill in the art reading Furutani and Scholz (in view of Harlow, Sambrook and the prior art) would simply not extrapolate the property of inducing an immune response to the target antigen/protein fused to PPIase in the PPIase fusion protein of Scholz to the chaperonin fusion protein of Furutani. This is because one of ordinary skill in the art would recognize the structural differences between a PPIase folding factor and the ring structure of chaperonins and would expect that the ring structure of chaperonins would affect the fusion protein's ability to induce an immune response to the target antigen by sequestering the target antigen so that it is not sufficiently exposed, thereby making it difficult for B-cell antigen receptors to recognize the target antigen protein. This same person would also immediately expect that antibodies to the target antigen protein would be difficult to obtain from such a fusion protein and therefore would not be motivated to use

Furutani's fusion protein in an immunizing composition for inducing an immune response to the sequestered target antigen protein.

In studying chaperonin fusion proteins, applicants discovered that the presence of the chaperonin ring structure protected the host cells from being killed in case the antigen protein fused to the chaperonin is toxic/harmful and also provided protection from rapid decomposition by proteases in the blood (see (a) and (d) on page 3 of the specification). Both of these advantageous properties are due to the sequestering nature of the chaperonin ring structure, a structural feature not shared with a foldase such as the PPIase used in Scholz's fusion protein. Furthermore, applicants surprisingly discovered using two chaperonins GroEL and TCP separately as examples that a fusion protein of these chaperonins with the serotonin receptor 5-HT1aR induced a better immune response than by 5-HT1aR alone (see Examples 1 and 2, Tables 1 and 2 on pages 40 and 46 of the present specification). The better immune response to a target antigen (serotonin receptor) fused to chaperonin would be completely unexpected to one of ordinary skill in the art as the sequestering nature of chaperonins would instead be expected to prevent sufficient exposure of the target antigen to, e.g., proteases and B-cell antigen receptors. This is particularly

true since applicants' results in Examples 1 and 2, pages 30-39 and 45 of the present specification, confirmed that the 5-HT1aR antigen protein sequestered in the chaperonin portion of the fusion protein is protected from specific protease digestion (PreScission and thrombin proteases), but not when denatured in the presence of urea or the chelating agent EDTA. Accordingly, the combination of Furutani, Scholz, Harlow and Sambrook simply cannot lead one of ordinary skill in the art to the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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